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IN THE UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF ALABAMA  
NORTHERN DIVISION

2005 JUN 23 A 11:17

BARBARA CLEM,

Plaintiff,

vs.

G.D. SEARLE, LLC (hereinafter  
"Searle") a subsidiary of PHARMACIA  
CORPORATION, (hereinafter  
"Pharmacia"), a Foreign Corporation;  
MONSANTO COMPANY; PFIZER  
INC., et al,

Defendants.

CIVIL ACTION NO. 2:05CV593-T

**ANSWER AND DEFENSES OF DEFENDANTS PHARMACIA CORPORATION,  
G.D. SEARLE LLC AND PFIZER INC. TO PLAINTIFF'S COMPLAINT**

Defendants Pharmacia Corporation (formerly "1933 Monsanto," see Paragraph 6, and improperly captioned in Plaintiff's Complaint as Monsanto Company), G.D. Searle LLC and Pfizer Inc. (collectively, "Defendants"), answer Plaintiff's Complaint in this action as follows:

**PRELIMINARY STATEMENT**

In November 2001, Bextra® was approved, as labeled, by the United States food and Drug Administration ("FDA") as a prescription medication. At times, Bextra® was advertised, promoted, marketed, and distributed in the United States by Defendants or one of their subsidiaries to be prescribed by healthcare providers who are authorized by law to prescribe medications in accordance with their approval by the FDA.

In April 2003, Pfizer Inc. ("Pfizer") merged with Pharmacia and the responsibilities for Bextra® were reallocated. G. D. Searle LLC ("Searle") is presently a wholly-owned third-tier subsidiary of Pharmacia, which in turn is a wholly-owned subsidiary of Pfizer.

This preliminary statement is incorporated by reference in its entirety in response to each and every paragraph of Plaintiff's Complaint.

**ANSWERING:**

**GENERAL ALLEGATIONS**

1. Answering Paragraph 1, no response is required. To the extent a response is deemed to be required, Defendants lack knowledge and information sufficient to form a belief as to the truth of the allegations contained in Paragraphs 1, and therefore deny the same.

2-3. Answering Paragraphs 2 through 3, Defendants lack knowledge and information sufficient to form a belief as to the truth of the allegations contained in Paragraphs 2 through 3, and therefore deny the same.

4. Answering Paragraph 4, Defendants admit that Searle is a wholly-owned subsidiary of Pharmacia Corporation, which is in turn a wholly-owned subsidiary of Pfizer. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Skokie, Illinois and is not registered to do business in Alabama. Defendants further admit that Searle can be served at the designated address. Defendants admit that at times Searle has manufactured, marketed, sold and distributed

Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA.

5. Answering Paragraph 5, Defendants admit that Pharmacia is a Delaware corporation. Defendants admit that Pharmacia is registered to do business in Alabama with a registered agent for service of process at the address alleged. Except as stated herein, Defendants deny the allegations of Paragraph 5.

6. Answering Paragraph 6, Defendants state that in 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, 1933 Monsanto changed its name to Pharmacia Corporation. Defendants state that Pharmacia Corporation (formerly known as 1933 Monsanto) is a Delaware Corporation. On February 9, 2000, Monsanto Ag Company was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold or distributed Bextra®. The 2000 Monsanto is not and has never been the parent of either Searle or Pharmacia. As the 2000 Monsanto does not and has not ever designed, produced, manufactured, sold, resold or distributed Bextra®, Defendants are therefore assuming that the 2000 Monsanto is not a party in this matter. Except as stated herein, Defendants deny the allegations of Paragraph 6.

7. Answering Paragraph 7, Defendants admit that Pfizer is a Delaware corporation. Defendants admit that Pfizer is registered to do business in Alabama with a registered agent for service of process at the address alleged. Defendants admit that, at

times, they marketed, distributed and sold Bextra® throughout the United States. Except as stated herein, defendants deny the allegations of Paragraph 7.

8. Answering Paragraph 8, Defendants state that this case is properly removed to the United States District Court for the Middle District of Alabama.

9. Answering Paragraph 9, Defendants state that the complaint satisfies the jurisdictional amount of federal diversity jurisdiction but have insufficient information or knowledge to form a belief as to the truth of the allegations contained in these paragraphs, and therefore deny the same.

10. Answering Paragraph 10, Defendants state that Bextra® is a prescription medication which is approved by the FDA for the indications described in its labeling.

11. Answering Paragraph 11, Defendants deny the allegations contained therein.

**ANSWERING:**

**BACKGROUND**

12. Answering Paragraph 12, Defendants state that Bextra® is a prescription medication which was, at all times relevant to this suit, approved by the FDA for use consistent with its prescribing information. Defendants admit that, at times, they manufactured, marketed, and distributed Bextra® in the United States to be prescribed by healthcare providers who are authorized by law to prescribe medications in accordance with their approval by the FDA. Except as stated herein, Defendants deny the allegations contained in Paragraph 12.

13. Answering Paragraph 13, Defendants deny the allegations contained therein.

14. Answering Paragraph 1, no response is required. To the extent a response is deemed to be required, Defendants lack knowledge and information sufficient to form a belief as to the truth of the allegations contained in Paragraphs 1, and therefore deny the same.

15. Answering Paragraph 15, Defendants lack knowledge and information sufficient to form a belief as to the truth of the allegations contained in Paragraph 15, and therefore deny the same.

16. Answering Paragraph 16, no response is required. To the extent a response is deemed to be required, Defendants lack knowledge and information sufficient to form a belief as to the truth of the allegations contained in Paragraph 16, and therefore deny the same.

17. Answering Paragraph 17, Defendants admit that, at times, they manufactured, marketed, and distributed Bextra® in the United States to be prescribed by healthcare providers who are authorized by law to prescribe medications in accordance with their approval by the FDA. Except as stated herein, Defendants deny the allegations of Paragraph 17.

18. Answering Paragraph 18, Defendants deny the allegations contained therein.

19. Answering Paragraph 19, no response is required.

**ANSWERING:**

**FIRST CAUSE OF ACTION: NEGLIGENCE**

20. Answering Paragraph 20, Defendants incorporate by reference their responses to the preceding Paragraphs as if fully set forth herein.

21. Answering Paragraph 21, Defendants deny the allegations contained therein.

22. Answering Paragraph 22, Defendants state that these allegations constitute Plaintiff's conclusions of law and therefore require no response. To the extent a response is deemed to be required, Defendants deny the allegations contained in Paragraph 22.

23-28. Answering Paragraphs 23 through 28, inclusive of all subparts, Defendants deny the allegations contained therein except as to the statement in Paragraph 28 that Plaintiff seeks an amount in excess of the jurisdictional limits of all lower courts, which requires no response.

**ANSWERING:**

**SECOND CAUSE OF ACTION: STRICT PRODUCTS LIABILITY**

**DEFECTIVE DESIGN**

29. Answering Paragraph 29, Defendants incorporate by reference their responses to the preceding Paragraphs as if fully set forth herein.

30-37. Answering Paragraphs 30 through 37, inclusive of all subparts, Defendants deny the allegations contained therein except as to the statement in Paragraph 37 that Plaintiff seeks an amount in excess of the jurisdictional limits of all lower courts, which requires no response.

**ANSWERING:**

**THIRD CAUSE OF ACTION: STRICT PRODUCTS LIABILITY**

**FAILURE TO WARN**

38. Answering Paragraph 38, Defendants incorporate by reference their responses to the preceding Paragraphs as if fully set forth herein.

39. Answering Paragraph 39, Defendants deny the allegations contained therein.

40-41. Answering Paragraphs 40 through 41, Defendants lack knowledge and information sufficient to form a belief as to the truth of the allegations contained in Paragraph 40 through 41, and therefore deny the same.

42. Answering Paragraph 42, Defendants state that the allegations contained therein constitute Plaintiff's conclusions of law and therefore require no response. To the extent a response is deemed to be required, Defendants deny the allegations contained in Paragraph 42.

43-48. Answering Paragraphs 43 through 48, inclusive of all subparts, Defendants deny the allegations contained therein except as to the statement in Paragraph 48 that Plaintiff seeks an amount in excess of the jurisdictional limits of all lower courts, which requires no response.

**ANSWERING:**

**FOURTH CAUSE OF ACTION: BREACH OF EXPRESS WARRANTY**

**OF MERCHANTABILITY**

49. Answering Paragraph 49, Defendants incorporate by reference their responses to the preceding Paragraphs as if fully set forth herein.

50. Answering Paragraph 50, Defendants admit to advertising Bextra® directly to consumers. Except as stated herein, Defendants deny the allegations contained in Paragraph 50.

51. Answering Paragraph 51, Defendants admit only that its sales representatives detailed Bextra® to physicians in a manner consistent with FDA-approved prescribing information. Except as stated herein, Defendants deny the allegations contained in Paragraph 51.

52-54. Answering Paragraphs 52-54, Defendants deny the allegations contained therein.

55. Answering Paragraph 55, no response is required.

**ANSWERING:**

**FIFTH CAUSE OF ACTION: BREACH OF IMPLIED WARRANTY**  
**OF MERCHANTABILITY**

56. Answering Paragraph 56, Defendants incorporate by reference their responses to the preceding Paragraphs as if fully set forth herein.

57-59. Answering Paragraphs 57 through 59, Defendants state that the allegations therein constitute Plaintiff's conclusions of law and therefore require no response. To the extent a response is deemed to be required, Defendants deny the allegations contained in Paragraphs 57 through 59.



60. Answering Paragraph 60, Defendants lack knowledge and information sufficient to form a belief as to the truth of the allegations contained in Paragraph 60, and therefore deny the same.

61-67. Answering Paragraphs 61 through 67, inclusive of all subparts, Defendants deny the allegations contained therein except as to the statement in Paragraph 67 that Plaintiff seeks an amount in excess of the jurisdictional limits of all lower courts, which requires no response.

**ANSWERING:**

**SIXTH CAUSE OF ACTION: FRAUD**

68. Answering Paragraph 68, Defendants incorporate by reference their responses to the preceding Paragraphs as if fully set forth herein.

69-82. Answering Paragraphs 69 through 82, inclusive of all subparts, Defendants deny the allegations contained therein except as to the statement in Paragraph 82 that Plaintiff seeks an amount in excess of the jurisdictional limits of all lower courts, which requires no response.

**ANSWERING:**

**SEVENTH CAUSE OF ACTION: NEGLIGENT MISREPRESENTATION**

83. Answering Paragraph 83, Defendants incorporate by reference their responses to the preceding Paragraphs as if fully set forth herein.

84-97. Answering Paragraphs 84 through 97, inclusive of all subparts, Defendants deny the allegations contained therein except as to the statement in Paragraph

97 that Plaintiff seeks an amount in excess of the jurisdictional limits of all lower courts, which requires no response.

**ANSWERING:**

**DEMAND FOR RELIEF**

Defendants deny that Plaintiffs are entitled to any of the relief demanded in the unnumbered WHEREFORE clause.

**DEFENSES:**

Discovery and investigation may reveal that any one or more of the following defenses should be available to Defendants in this matter. Defendants therefore assert the following defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Defendants will withdraw any of these defenses as may be appropriate.

**FIRST DEFENSE**

Plaintiff's Complaint fails to state a claim against Defendants upon which relief can be granted.

**SECOND DEFENSE**

Plaintiff's claims may be barred by the applicable statute of limitations or by the equitable doctrines of laches and estoppel.

**THIRD DEFENSE**

Plaintiff's injuries and damages, if any, were solely caused by the acts or omissions, abuse or misuse, negligence or fault or otherwise, of third persons or parties

over whom Defendants had no control or right to control and whose actions are not, therefore, imputable to Defendants.

#### **FOURTH DEFENSE**

Defendants made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Plaintiff herein. Additionally, as a manufacturer and not a seller, Defendants are not subject to liability for implied warranties without privity, i.e., proof of direct and specific transactions between Plaintiff and Defendants. If any such warranties were made, whether express or implied, which Defendants specifically deny, then Plaintiff failed to give timely notice of any breach thereof as required under Ala. Code § 7-2-607.

#### **FIFTH DEFENSE**

Plaintiff's injuries and damages, if any, were proximately caused by the negligence or fault of Plaintiff or those acting at the direction or control of Plaintiff, whose contributory negligence or fault is sufficient to bar any recovery by Plaintiff.

#### **SIXTH DEFENSE**

Plaintiff's injuries, if any, were due to an idiosyncratic reaction to Bextra®, or by an unforeseeable illness, unavoidable accident, or pre-existing condition, without any negligence or culpable conduct by Defendants.

#### **SEVENTH DEFENSE**

Plaintiff failed to exercise reasonable care and diligence to mitigate injuries and damages, if any.

#### **EIGHTH DEFENSE**

Plaintiff's claims are barred or limited to a product liability failure to warn claim

because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

**NINTH DEFENSE**

Bextra® is safe when used as directed, and Defendants reasonably assumed that their warnings would be read and heeded; therefore, Bextra® is neither defective nor unreasonably dangerous pursuant to Restatement (Second) of Torts § 402A, Comment j.

**TENTH DEFENSE**

As a prescription pharmaceutical, Bextra® falls within the ambit of the Food, Drug and Cosmetic Act and regulations promulgated by the Food and Drug Administration. Accordingly, Plaintiff's claims have been preempted under the Supremacy Clause of the U.S. Constitution.

**ELEVENTH DEFENSE**

Bextra® and Defendants' actions conformed to the state of the art of medical and scientific knowledge at all times relevant to this lawsuit and Bextra® complied with applicable product safety statutes and regulations as described in Restatement (Third) of Torts: Products Liability § 4.

**TWELFTH DEFENSE**

Plaintiff's claims are barred by assumption of the risk.

**THIRTEENTH DEFENSE**

Bextra® provides net benefits for a class of patients, and is accompanied by appropriate warnings and instructions. Accordingly, Defendants plead the Learned Intermediary Doctrine, as applied to prescription pharmaceuticals at Restatement (Third)

of Torts § 6, comment f. Defendants further say they made available to physicians all appropriate disclosures.

#### **FOURTEENTH DEFENSE**

The imposition of punitive damages pursuant to current Alabama law violates the Due Process and Equal Protection provisions of U.S. Const. Amend. XIV; to wit, these Defendants have not been given fair notice of the standard of conduct which could subject them to a claim for punitive damages, and have not been given fair notice of the amount of punitive damages that may accompany a finding of liability. Alabama's current laws regarding punitive damages do not serve a rational or legitimate state interest.

#### **FIFTEENTH DEFENSE**

Plaintiff's claims for punitive damages would violate these Defendants' rights under the Fifth, Sixth, Seventh, Eighth, and Fourteenth Amendment of the Constitution of the United States of America and Article 1, Sections 1, 2, 6, 11, 13, 15, 27, and 35 of the Constitution of Alabama.

#### **SIXTEENTH DEFENSE**

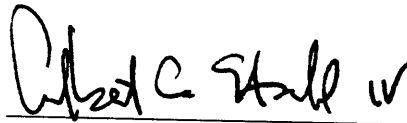
Plaintiff's claims for punitive damages are limited or barred by the standards governing exemplary damages awards which arise under the United States Constitution and decisions of the United States Supreme Court including, but not limited to: *BMW of North America v. Gore*, 116 U.S. 1589 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003). Further, Plaintiff's claims for punitive damages are limited or barred by the standards governing exemplary damages, which arise under the

Constitution of Alabama, Alabama state statutes, and the decisions of Alabama state courts.

**JURY DEMAND**

Defendants demand a trial by jury on all issues so triable.

WHEREFORE, Defendants respectfully request that this action be dismissed with prejudice and that they be awarded their costs and any other forms of relief to which they may be entitled.

A handwritten signature in black ink, appearing to read "Lawrence B. Clark", is written over a horizontal line.

LAWRENCE B. CLARK  
GILBERT C. STEINDORFF, IV  
WENDY A. MADDEN  
Attorneys for G.D. Searle LLC, Pharmacia  
Corporation, and Pfizer Inc.

OF COUNSEL:

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205.250.5000

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that the above and foregoing pleading has been served on all counsel of record by depositing a copy of same in the United States mail, properly addressed and postage prepaid on this 23<sup>rd</sup> day of June, 2005

Navan Ward, Jr.

Andy D. Birchfield, Jr.

Paul Sizemore

BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C.

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